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Mineral Acids
Interim Registration Review Decision
Case Number 4064

March 2018

Approved by: _____
Anita Pease
Acting Director
Antimicrobials Division

Date: 3/26/18

Approved by: _____
Yu-Ting Guilaran, P.E.
Director
Pesticide Re-evaluation Division

Date: 3/12/18

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Mineral Acids Registration Review Team

Human Health & Environmental Effects

Antimicrobials Division
Laura Parsons
Timothy Dole
Jonathan Chen
Timothy Leighton
Timothy McMahon

Environmental Fate and Effects Division
Christine Hartless

Health Effects Division
Elissa Reaves

Risk Management
Rachel Ricciardi
Rick Fehir
Cathryn Britton
Nicole Zinn

Office of General Counsel
Philip Ross

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I. Introduction

This document is the Environmental Protection Agency's (EPA or the Agency) *Interim Registration Review Decision* (ID) for mineral acids and is being issued pursuant to 40 CFR sections 155.56 and 155.58. A registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may: 1) require new risk mitigation measures; 2) impose interim risk mitigation measures; 3) identify additional data or other information required to complete the review; and 4) include schedules for submitting the required data, conducting the new risk assessment, and completing the registration review. For further information on mineral acids, additional documents can be found in EPA's public docket (EPA-HQ-OPP-2008-0766) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandated the continuous review of existing pesticides. All pesticides distributed or sold in the United States generally must be registered by the EPA based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at http://www2.epa.gov/pesticide-reevaluation. In 2006, the Agency implemented the registration review program pursuant to FIFRA section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

EPA is issuing an interim registration review decision, which includes risk mitigation for mineral acids, so that it can move forward with aspects of the registration review that are complete. The Agency is currently working with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (together, the Services) to develop methodologies for conducting national endangered species assessments for pesticides. Therefore, although EPA has not yet fully evaluated risks to threatened and endangered (listed) species at this time, the Agency will complete its endangered species assessment and any necessary consultation with the Services for mineral acids prior to completing the mineral acids registration review. Likewise, the Agency will complete endocrine screening for mineral acids, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) 408(p), before completing this registration review. Lastly, EPA will determine whether additional pollinator exposure and effects data are necessary to make a final registration review decision for mineral acids and, if so, will issue a data call-in notice to obtain any such data prior to completing the mineral acids registration review. See Appendices D and E, respectively, for additional information on the endangered species assessment and the endocrine screening for the registration review of mineral acids.

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Summary of Mineral Acids Registration Review

Products containing mineral acids are antimicrobial pesticides registered for use as sanitizers, disinfectants, virucides, disinfectants, microbiocides/microbiostats, and fungicides. The mineral acids chemical case includes the following active ingredients: hydrochloric acid, phosphoric acid, sulfuric acid and sodium bisulfate. Registered antimicrobial uses include those in eating establishments, eating establishment equipment/utensils, food processing plant equipment, animal premises treatment, household/domestic dwellings such as kitchens, bathroom premises/hard surfaces, refuse/solid waste sites, toilet bowls, urinals, a variety of disinfectant uses (hospital, agricultural, and dairy) and mushroom houses. There are also three herbicidal products registered for the conventional use of sulfuric acid as a potato vine desiccant. The pesticide products are formulated as emulsifiable concentrates, soluble concentrates/liquids, ready-to-use liquids, and crystalline products. Mineral acid products were first registered as pesticides in 1958 and a Reregistration Eligibility Decision (RED) was conducted for mineral acids in December 1993.

This document is organized in five sections: the *Introduction,* which includes this summary and a summary of public comments and EPA's responses; *Use and Usage*, which describes how and why mineral acids are used and summarizes data on their use; *Scientific Assessments*, which summaries EPA's risk and benefits assessments, any revisions to previous risk assessments, and risk conclusions; the *Interim Registration Review Decision*, which describes the mitigation measures required to address risks of concern and the regulatory rationale for EPA's interim registration review decision; and, last, the *Next Steps and Timeline* for completion of this registration review.

Pursuant to 40 CFR section 155.50, EPA formally initiated registration review for the mineral acids chemical case (case 4064) in 2008. The following highlights significant events that have occurred during the registration review of mineral acids and can be found in EPA's public docket, EPA-HQ-OPP-2008-0766, accessed at www.regulations.gov:

- December 2008 - Publication of the *Mineral Acids Summary Document* for a 60-day public comment period. The Summary Document included the Preliminary Work Plan (PWP) and was accompanied by the: *Summary of Human Health Effects Data for the Mineral Acids Registration Review Decision Document*; *Sulfuric acid on potato vines: Registration Review Scoping Document for Human Health Assessments*; *Summary of Product Chemistry, Environmental Fate, and Ecotoxicity Data for the Hydrochloric Acid Registration Review Decision Document*; *Summary of Product Chemistry, Environmental Fate, and Ecotoxicity Data for the Phosphoric Acid Registration Review Decision Document*; *Summary of Product Chemistry, Environmental Fate, and Ecotoxicity Data for the Sulfuric Acid Registration Review Decision Document*; *Registration Review – Preliminary Problem Formulation for the Ecological Risk Assessment of Potato Desiccant Use of Sulfuric Acid*; and *Summary of Product Chemistry, Environmental Fate, and Ecotoxicity Data for the Sodium Bisulfate Registration Review Decision Document*.

- June 2009 - Publication of the *Mineral Acids Final Work Plan* (FWP). During the PWP 60-day comment period, comments were received from Syngenta and the United States

Department of Agriculture (USDA). The comments did not change the data needs, planned risk assessments, or the timeline for the mineral acids registration review, thus, the FWP did not modify the PWP.

- August/October 2011 - Generic Data Call-Ins (GDCIs) for mineral acids were issued (GDCI-078001-995; GDCI-076001-996; GDCI-045901-997; GDCI-076001-1044; GDCI-045901-1046). The GDCI included Product Use Information (Guideline Number [GLN] 875.1700) and Indoor Inhalation Exposure (GLN 875.1400) data. Some of these data are currently under development by the Antimicrobial Exposure Assessment Task Force II (AEATF II). Upon receipt and review of these data, the Agency may, as appropriate, reevaluate the immersion and coarse spray treatment.

- September 2016 - The Agency published the *Mineral Acids Human Health and Ecological Preliminary Risk Assessment for Registration Review for the Antimicrobial and Conventional Uses* for a 60-day public comment period. No public comments were received.

- December 2017 - The Agency published the *Mineral Acids Proposed Interim Registration Review Decision* for a 60-day public comment period. Four public comments were received. Three of the four comments did not pertain to the chemical case and were inadvertently posted to the mineral acids docket. The fourth comment was posted by the Integrated Pest Management (IPM) Center's Information Network Coordinator for the Pacific Northwest through the Integrated Plant Protection Center (IPPC) of the Department of Environmental and Molecular Toxicology at Oregon State University. The comment stated that the mitigation measures for the conventional uses are not expected to impact potato growers in the Pacific Northwest since sulfuric acid is not commonly applied by air and that it is considered too heavy and dangerous for this application method. The Agency thanks IPPC for its comment. No changes were made to the risk mitigation or registration review schedule of mineral acids, thus, the *Mineral Acids Interim Registration Review Decision* did not include any modifications to what was proposed in the *Mineral Acids Proposed Interim Registration Review Decision*.

- March 2018 - The Agency has completed the *Mineral Acids Interim Registration Review Decision* and will announce its availability in the Federal Register in the docket EPA-HQ-OPP-2008-0766.

II. Use and Usage

Products containing hydrochloric acid as an active ingredient (a.i.) (PC Code 045901) are registered for antimicrobial use as disinfectants, sanitizers, and deodorizers for toilet bowls and urinals. Applications are primarily made through a child-proof squeeze bottle. The labels for these antimicrobial products prohibit the use of the product on wash bowls, floors, countertops and other hard surfaces. However, EPA Reg. No. 88141-1's application method is through spray, wipe or immersion.

Products containing phosphoric acid (PC Code 076001) are registered for use in residential premises as a disinfectant and sanitizer for antimicrobial treatment primarily in bathrooms and at least one product (Reg. No. 88141-1) is registered for use in food preparer sinks or kitchens on hard surfaces such as sinks, countertops, floors, toilets, etc. using mop and trigger pump spray and wipe application techniques. This a.i. is also contained in antimicrobial products registered for use in clean-in-place (CIP) scenarios for dairy processing equipment or utensils; CIP, coarse spray, mop and wipe applications for agricultural premises and equipment; and food handling/storage establishments, premises, and equipment (e.g., EPA Reg. No. 82808-3).

Products containing sulfuric acid (PC Code 078001) are registered for use as an antimicrobial pesticide in CIP scenarios for food processing and dairy equipment, and as a conventional pesticide to be used only west of the Mississippi River as a desiccant of potato vines. Sulfuric acid stops tuber development at the end of the season to optimize harvesting and enhance tuber quality for storage or processing. There are three conventional end-use pesticide products and they are all classified as restricted use pesticides (RUPs). Two desiccant applications may be required depending on the potato cultivar grown and conditions such as weather and vine growth. Sulfuric acid is caustic and corrosive, but has no rotational crop restrictions. It provides rapid vine-kill, although tuber maturation may be reduced. Vine desiccation is performed at the end of the growing season, typically the end of August to the end of September (14-16 weeks after planting).

The available usage data indicate that potatoes are treated with sulfuric acid at an average rate of 182 pounds of active ingredient (lbs. a.i.) per acre.[1] Overall usage is relatively significant with an average of more than seven percent of the national percent crop treated (PCT) over the years 2010-2014. Generally, only one application is made per year. The large majority of use comes from the state of Idaho, though Colorado also shows a high percent crop treated with fewer acres grown. Inconsistent and minor usage in California and Nebraska is also reported during the timeframe. Currently, sulfuric acid may be applied by ground or by air. According to the available usage data, sulfuric acid is used on a small percent of potato acreage with less than one percent of usage coming from aerial applications.

Sodium bisulfate (PC Code 073201) is contained in one antimicrobial product (EPA Reg. No. 4822-407) registered for use for ammonia control, bacterial management, and pH control in poultry houses. The pesticide is sold as a crystalline/solid formulation packaged in 50 lb bags and the applicator spreads the sodium bisulfate over the top of poultry litter in poultry houses. Another antimicrobial product containing sodium bisulfate (EPA Reg. No. 33907-3) is registered for use as a toilet bowl cleaner where the user pours a half cup of granular in the toilet bowl.

III. Scientific Assessments

A. Human Health Risk

A summary of the Agency's human health risk assessment is presented below in support of the

[1] USEPA, 2017. *Sulfuric Acid Usage and Qualitative Impact Analysis (PC #078001)*. Yourman, Leonard.

registration review of mineral acids. For detailed discussions of all aspects of the human health assessment, see the *Sulfuric Acid – Reevaluation of the Point of Departure (POD) and Uncertainty Factors used for Inhalation Risk Assessment*[2], *Summary of Human Health Effects Data for the Mineral Acids Registration Review Decision Document*, *Sulfuric acid on potato vines: Registration Review Scoping Document for Human Health Assessments* and *Mineral Acids Human Health and Ecological Preliminary Risk Assessment for Registration Review for the Antimicrobial and Conventional Uses* located in the public docket at EPA-HQ-OPP-2008-0766.

In the *Mineral Acids Human Health and Ecological Preliminary Risk Assessment for Registration Review for the Antimicrobial and Conventional Uses*, the Agency calculated margin of exposures (MOEs) for the antimicrobial uses of mineral acids. The residential hydrochloric acid inhalation MOE for spraying and mopping is 1900 or higher, and the occupational inhalation MOE for spraying and mopping is 390 or higher, which are above the target MOE of 300[3] and do not trigger a risk concern. The Agency also calculated the occupational and residential phosphoric acid inhalation MOEs for spraying and mopping applications by bridging data from a sulfuric acid study. The MOEs for residential and occupational spraying using a trigger pump sprayer indicate potential risks of concern (MOEs range from 2 to 17 with a Target MOE of 30).[4] A qualitative assessment was completed for one sulfuric acid product (EPA Reg. No. 4959-41) for which the label states minimal amounts of liquid concentrate are poured. The Agency determined that the pouring process into the food processing and dairy equipment to be sanitized would result in minimal inhalation exposure. However, two other antimicrobial products (EPA Reg. Nos. 833-9 and 90863-1) are applied via immersion and coarse spray. As a result, the inhalation MOEs are anticipated to be similar to those estimated for phosphoric acid, which indicate potential risks of concern. As for sodium bisulfate, the a.i. is Generally Recognized as Safe (GRAS) by the Food and Drug Administration (FDA) for food use. Sodium bisulfate completely dissociates into Na^+, H^+ and SO_4^{2-} ions; thus, these salts are not of a toxicological concern. Sodium bisulfate is corrosive to the eyes; however, the products are labeled with DANGER and personal protective equipment (PPE) is required on the label. EPA revised the inhalation toxicological endpoints as part of this registration review. The toxicological database on mineral acids is adequate to support this registration review case. Additionally, for the human health risk assessment for both antimicrobial and conventional uses, no dietary risk assessment was necessary. The Food and Drug Administration (FDA) considers the mineral acids to be generally recognized as safe (GRAS) for use in foods. For the antimicrobial uses of mineral acids, mineral acids concentrations are significantly diluted,

[2] EPA's memorandum is located on the mineral acids registration review docket at EPA-HQ-OPP-2008-0766 in www.regulations.gov: Memorandum, September 2017. *Sulfuric Acid – Reevaluation of the Point of Departure (POD) and Uncertainty Factors used for Inhalation Risk Assessment*. DP#442869.

[3] In the *Mineral Acids Human Health and Ecological Preliminary Risk Assessment for Registration Review for the Antimicrobial and Conventional* Uses, the Agency inadvertently stated that hydrochloric acid's target MOE was 100. The Agency has updated the target MOE to 300 based on the following uncertainty factors: 10x (lack of a No-Observed-Adverse-Effect-Level [NOAEL]), 3x (interspecies extrapolation rat to human with HEC [Human Equivalent Concentration]), and 10x intraspecies variation (in human response to irritation).

[4] In the *Mineral Acids Human Health and Ecological Preliminary Risk Assessment for Registration Review for the Antimicrobial and Conventional* Uses, the Agency stated that the Target MOE for phosphoric acid was 1000. The uncertainty factors were reevaluated and the Target MOE is 30. Section III. A. 2. further discusses the decision, as well as EPA's memorandum *Sulfuric Acid – Reevaluation of the Point of Departure (POD) and Uncertainty Factors used for Inhalation Risk Assessment*.

dissociate in water to salts, and there are no oral toxicity endpoints of concern. The food surface sanitizer use may be expected to result in the introduction of low concentrations of mineral acids into drinking water and food supply; however, exposure via food or drinking water consumption is not a concern due to the low toxicity of mineral acids, the already insignificant risk from food sources, and existing tolerance exemptions.[5]

The Agency did not require additional toxicity data in the mineral acids registration review case. The Agency reviewed the historical toxicological database supporting the original mineral acids RED, which was comprised mostly of published and unpublished studies obtained directly from open literature. Since the mineral acids registrants did not submit any additional inhalation toxicity data, and the Agency did not identify an appropriate phosphoric acid inhalation toxicity study, the Agency used toxicological data from a sulfuric acid study that provided a conservative toxicological endpoint for the phosphoric acid inhalation risk assessment. These data were able to be bridged because phosphoric acid and sulfuric acid are strong acids whose aerosol growth and deposition processes are likely to be similar.

All four a.i.s of the mineral acids case are corrosive to the eyes. In addition, the mineral acids are corrosive to the skin, except for sodium bisulfate. The a.i.s have been placed in Toxicity Category I, indicating the greatest degree of acute toxicity for eye and dermal irritation effects. Sulfuric acid is in Toxicity Category I for inhalation, II for oral and III for dermal. The mineral acids, otherwise are moderately acutely toxic, and are placed in Toxicity Category III (on a scale of I to IV) for acute oral and dermal effects.

1. Summary of Human Health Risks - Antimicrobial Uses

The Agency has determined that there are potential inhalation risks of concern for the residential and occupational handler spray and wipe scenario uses of phosphoric acid, and for the occupational handler use of sulfuric acid in EPA Reg. No. 90863-1.

Residential Handler Risks:

Hydrochloric acid application is almost exclusively used through a child proof squeeze bottle where the user is instructed to apply the product onto the interior of the toilet surfaces and brush the toilet with a bowl brush. During product application, the applicator is required by the label to wear goggles or safety glasses, protective clothing and rubber (or chemical resistant) gloves. According to the *Mineral Acids Human Health and Ecological Preliminary Risk Assessment for Registration Review for the Antimicrobial and Conventional Uses*, there are minimal inhalation exposure concerns for the squeeze bottle scenario use. However, one product (EPA Reg. No. 88141-1) is applied using a trigger pump spray and wipe, and mop to hard surfaces such as appliances, food preparation and storage areas, countertops, floors, etc. The Agency conducted a quantitative residential assessment for this use based on AEATF II inhalation exposure data and the Agency used information on the amount of product applied from an Antimicrobial Exposure Joint Venture (AEJV) survey. The results, shown in **Table 1**, indicate that inhalation risks to homeowners mopping floors and spraying hard surfaces are not of concern (MOE is 130,000 for mopping and 1,900 for spraying, with a Target MOE of 300). In addition, it is reasonable to

[5] See Section III. A. 8. for more information regarding mineral acids' tolerance exemptions.

assume that a homeowner would disinfect both floors and hard surfaces on the same day, and therefore, a total daily MOE is also provided which indicate no risks of concern (Total daily inhalation MOE is 1,900).

Table 1- Residential Handler Inhalation MOEs for the Residential Use of Hydrochloric Acid

Scenario	Application Rate	Amount of Product Applied (gal/day)	Amount ai Handled (lb)	Inhalation Unit Exposure (8 hr TWA* mg/m^3/lb ai)	Inhalation Exposure (8 hr TWA* mg/m^3)	Inhalation MOE (Target MOE=300)
Mopping floors	0.66% ai by wt	0.26	0.015	0.0093	0.00014	130,000
Spray & wipe		0.06	0.0034	2.8	0.0094	1,900
Total daily cleaning		Total daily MOE = 1/((1/MOEmop + 1/MOEwipe))				1,900

* TWA = Time Weighted Average.

Phosphoric acid potential exposure pathways for residential uses include trigger pump spray and wipe as well as mopping floors. Based on review of the product labels for phosphoric acid, EPA conducted a risk assessment for the potential residential handler inhalation exposure that may occur during trigger pump spray and wipe and mop applications. The inhalation risk to homeowners mopping floors are not of concern, shown in **Table 2** (MOE is 1100 with a Target MOE of 30). However, the inhalation risks for a homeowner spraying phosphoric acid onto hard surfaces is a potential risk of concern (MOE is 17 with a Target MOE of 30). In addition, it is reasonable to assume that a homeowner would disinfect both floors and hard surfaces on the same day, and therefore, a total daily MOE is 17, as the risk-driver for the total daily cleaning is the use of the trigger pump sprayer.

Table 2 - Residential Handler Inhalation MOEs for the Residential Use of Phosphoric Acid

Scenario	Application Rate	Amount of Cleaner Applied (gal/day)	Amount ai Handled (lb)	Inhalation Unit Exposure (8 hr TWA* mg/m^3/lb ai)	Inhalation Exposure (8 hr TWA* mg/m^3)	Inhalation MOE (Target MOE=30**)
Mopping floors	1.64% ai by wt	0.26	0.036	0.0093	0.00034	1100
Spray & wipe		0.06	0.0083	2.8	0.023	**17**
Total daily cleaning		Total daily MOE = 1/((1/MOEmop + 1/MOEwipe))				**17**

* TWA = Time Weighted Average.
** Memorandum, September 2017. *Sulfuric Acid – Reevaluation of the Point of Departure (POD) and Uncertainty Factors used for Inhalation Risk Assessment*. DP#442869.
Note: MOEs in bold type represent potential risks of concern.

Antimicrobial sulfuric acid products (EPA Reg. Nos. 833-9 and 4959-41) are currently registered for occupational use only in food processing and dairy equipment.

Sodium bisulfate's residential use antimicrobial product is a toilet bowl cleaner. According to the *Mineral Acids Human Health and Ecological Preliminary Risk Assessment for Registration Review for the Antimicrobial and Conventional Uses*, there are no toxicological concerns for the use of sodium bisulfate.

Residential Post-Application Risks:

There are no residential post-application risks of concern for the antimicrobial uses of mineral acids.

Occupational Handler Risks:

The Agency did not require exposure data and/or risk assessments for products such as child proof squeeze bottles for toilets using hydrochloric acid and phosphoric acid or CIP antimicrobial uses for sulfuric acid, as these uses are expected to result in minimal inhalation exposure. However, one sulfuric acid product (EPA Reg. No. 90863-1) includes an application via immersion and coarse spray at a dilution rate of 1.97% sulfuric acid, which may result in occupational exposure. There are no toxicological concerns for sodium bisulfate.

The Agency conducted risk assessments for hydrochloric and phosphoric acid products for trigger pump spray and wipe and mop applications. The inhalation MOE for hydrochloric acid for the total daily cleaning activities (the sum of the inhalation exposures estimated for mopping, and trigger pump spray and wipe) is 390 (target MOE of 300) and does not trigger a risk of concern (**Table 3**).

Table 3 - Occupational Handler Inhalation MOEs for the Occupational Use of Hydrochloric Acid

Scenario	Application Rate	Amount of Cleaner Applied (gal/day)	Amount ai Handled (lb)	Unit Exposure (8 hr TWA* mg/m^3/lb ai)	Inhalation Exposure (8 hr TWA* mg/m^3)	MOE (Target MOE = 300)
Mopping floors	0.66% ai by wt	2	0.11	0.0093	0.001	24000
Spray & wipe		0.414	0.023	2.8	0.065	390
Total daily cleaning		Total daily MOE = $1/((1/MOE_{mop} + 1/MOE_{wipe}))$				390

* TWA = Time Weighted Average.

However, **Table 4** shows that the total daily cleaning activities for phosphoric acid results in potential inhalation risks of concern due to the spray and wipe scenario (MOE is 2 and Target MOE is 30). A risk assessment was also conducted on low pressure hand wand phosphoric acid data available in the Pesticide Handlers Exposure Database (PHED). The assessment found that the phosphoric acid inhalation MOE for the low pressure hand wand spray is not a risk of concern (MOE is 2500 and Target MOE is 30). However, because the PHED data are older data from mostly outdoor applications that utilized filter respirator monitoring methodology, the low

pressure hand wand scenario may, as appropriate, be reassessed by the EPA using new data to be monitored by the AEATF II in the future.

Table 4 - Occupational Handler Inhalation MOEs for the Occupational Use of Phosphoric Acid

Scenario	Application Rate	Amount of Solution Applied (gal/day)	Amount ai Handled (lb)	Unit Exposure (8 hr TWA* mg/m^3/lbai)	Inhalation Exposure (8 hr TWA* mg/m^3)	MOE (Target MOE = 30**)
Low Pressure Hand Wand	0.061% ai by wt	10	0.051	0.0029	0.00015	2500
Mopping floors	1.64% ai by wt	2	0.28	0.0093	0.0026	150
Spray & wipe		0.414	0.058	2.8	0.16	**2**
Total daily cleaning[G]		Total daily MOE = $1/(1/MOE_{mop} + 1/MOE_{wipe})$				**2**

* TWA = Time Weighted Average.
** Memorandum, September 2017. *Sulfuric Acid – Reevaluation of the Point of Departure (POD) and Uncertainty Factors used for Inhalation Risk Assessment*. DP#442869.
Note: MOEs in bold type represent potential risks of concern.

For sulfuric acid and sodium bisulfate, only a qualitative risk assessment was conducted due to the lack of toxicity for sodium bisulfate and labeled PPE, REIs (restricted entry intervals), and closed systems for sulfuric acid (with the exception of the antimicrobial immersion and course spray application). Sulfuric acid EPA Reg. Nos. 833-9 and 90863-1 were registered in 2014 and 2015, respectively. Both products are used as a CIP for food processing and dairy equipment; however, EPA Reg. No. 90863-1 also includes an application via immersion and coarse spray. Since the inhalation MOEs are anticipated to be similar to those of phosphoric acid (see **Table 4**), the spray and wipe scenario for EPA Reg. No. 90863-1 is a potential risk of concern. The Agency required Product Use Information (GLN 875.1700) and Indoor Inhalation Exposure (GLN 875.1400) data in the registration review GDCIs; however, these data are currently under development by the AEATF II. Upon receipt and review of these data, the Agency may, as appropriate, reevaluate the immersion and coarse spray treatment.

Occupational Post-Application Risks:

There are no occupational post-application risks of concern for the antimicrobial uses of mineral acids.

2. Characterization of Human Health Risks - Antimicrobial Uses

The EPA has reviewed the AEATF II handler exposure studies used in the assessment of hydrochloric and phosphoric acids for uncertainties associated with the use of surrogate exposure data. The reviews are located on the Agency's Human Studies Review Board (HSRB) website.[6] As this interim decision has previously stated, the mineral acids GDCIs required Product Use Information (GLN 875.1700) and Indoor Inhalation Exposure (GLN 875.1400) data, which

[6] https://www.epa.gov/osa/human-studies-review-board

remain to be submitted to the Agency; these data are currently under development by the AEATF II. Upon receipt and review of these data, the Agency may, as appropriate, reevaluate the immersion and coarse spray treatment.

The Agency used AEJV survey results that collected data on the amount of product handled by homeowners on the following surfaces: sinks, tub/shower/shower door, and counter. It is reasonable to assume that a handler would potentially clean all surfaces in a single day, and therefore, the exposure/risk has also been presented as the sum of a "daily cleaning" event. However, although the Agency used AEJV survey results, there are uncertainties because the results of the survey are still under review, and at this time, maximum amounts handled are used, which may overestimate exposure.

The low pressure hand wand PHED inhalation unit exposure data are used to assess the dairy and food processing and equipment treatments; however, this scenario from PHED is not representative of indoor uses and the inhalation data collected using a methodology (filter respirator) are no longer used, resulting in uncertainties. The AEATF II plans to conduct an exposure study for manual and mechanical hand held sprayers.

In the *Mineral Acids Human Health and Ecological Preliminary Risk Assessment for Registration Review for the Antimicrobial and Conventional Uses*, the Agency selected an open literature 78-week inhalation study to bridge toxicological data from sulfuric acid to phosphoric acid (Alarie et al., 1973).[7] However, there are some differences between the phosphoric and sulfuric acids exposures and application rates. The exposures for phosphoric acid in **Table 4** represent a trigger pump sprayer on hard surfaces, while the sulfuric acid labeled uses are for immersion and coarse spray. Phosphoric acid is applied at a rate of 1.64% a.i. for the trigger pump sprayer and sulfuric acid is applied at a rate of 1.97% a.i. for the coarse spray (EPA Reg. No. 90863-1). Since the mineral acids registrants did not submit any additional inhalation toxicity data, and the Agency did not identify an appropriate phosphoric acid inhalation toxicity study, the Agency used the Alarie et al. (1973) study to provide a conservative toxicological endpoint for the phosphoric acid inhalation risk assessment. Unless phosphoric acid inhalation toxicological data are submitted, there are uncertainties, and the Agency will continue to bridge the sulfuric acid data to the phosphoric acid inhalation risk assessment.

In Alarie et al. (1973), nine cynomolgus monkeys (five males and four females or vice versa) per group were exposed to H_2SO_4 concentrations of 0, 0.38, 0.48, 2.43, and 4.79 mg/m^3 continuously for 78 weeks. In the *Mineral Acids Human Health and Ecological Preliminary Risk Assessment for Registration Review for the Antimicrobial and Conventional Uses*, the Agency stated that monkeys demonstrated a Lowest Observed Adverse Effect Concentration (LOAEC) at 0.38 mg/m^3 based on increased incidence of bronchiolar epithelial hyperplasia and thickening of the bronchiolar walls and higher respiratory rate. This concentration was selected as the point of departure (POD) for risk assessment, and an uncertainty factor of 10X was applied to address the uncertainty associated with using a LOAEC, an uncertainty factor of 10X was applied to address the interspecies extrapolation (animal to human extrapolation), and an uncertainty factor of 10X

[7] Alarie, et al. (1973). *Long-term continuous exposure to sulfuric acid mist in cynomolgus monkeys and guinea pig*. Arch Environ Health. Volume 27; pp 16-24; MRID 49952801.

was applied to address intraspecies variability (within human variation). These factors yielded a target MOE of 1000.

Since the *Mineral Acids Human Health and Ecological Preliminary Risk Assessment for Registration Review for the Antimicrobial and Conventional Uses* was published in September 2016, the Agency has reevaluated the uncertainty factors. Risk mitigation discussions with phosphoric acid registrants, including the Phosphoric Acid Steering Committee/Joint Venture, and EPA Reg. No. 90863-1's Phresh Technologies, LLC prompted the Agency to consider reducing the uncertainty factors for the monkey study. Upon reevaluation by the Agency, EPA made the following conclusions: The interspecies extrapolation was reduced from an uncertainty factor of 10X to 1X because: (1) the effect of mineral acids is point of contact and not systemic and (2) the study is based on a primate study. Also, due to the highly conservative nature of the Alarie et al. (1973) study design and the low severity of the effects in some, but not all the animals[8], the LOAEL to NOAEL factor of 10X was reduced to 3X. The uncertainty factor of 10X to address intraspecies variability was still applied. As a result, these factors yielded a target MOE of 30. For a more detailed discussion of the uncertainty factors, please see the memorandum *Sulfuric Acid – Reevaluation of the Point of Departure (POD) and Uncertainty Factors used for Inhalation Risk Assessment*.

Some EPA registered phosphoric acid products are applied via foam (e.g. EPA Reg. No. 1677-100). The Agency notes that currently there is no inhalation exposure assessment available on the foam application method; however, the foam application method is anticipated to have less exposure than the spray and wipe application method. Still, the foam application method is considered an aerosol application and will be treated as such. As a result, the foam application method inhalation MOEs are potential risks of concern.

3. Summary of Human Health Risks - Conventional Uses

Residential Risks

There are no conventional residential uses for sulfuric acid. Therefore, there are no residential handler or post-application risks of concern from the conventional use of sulfuric acid.

Occupational Handler Risks and Occupational Post-Application Risks

Concentrated sulfuric acid (93%) is a restricted use pesticide (RUP), applied by certified applicators wearing extensive PPE to desiccate potato vines prior to harvest. Sulfuric acid is corrosive to the skin and eyes. There is label required PPE, including chemical-resistant

[8] In Alarie et al. (1973), monkeys were exposed to sulfuric acid mist continuously for 24 hours/day, 7 days/week for 78 weeks. This daily exposure exceeds estimates used in the risk assessment. For the occupational handlers, the Agency assumes 8 hours/day and 5 days/week for a continuous period of employment greater than 6 months (long term). For the residential handlers, the Agency assumes a couple of exposure days per week (short term). In addition, treatment effects at the lowest concentration in the monkey study included slight bronchiolar epithelial hyperplasia in five of nine animals, slight thickening of the walls of the respiratory bronchioles in three of nine animals, and slight focal bronchial epithelial hyperplasia in four of nine animals. These low-grade effects are typical for chronic exposure to an inhaled irritant. In a companion study of guinea pigs, no histopathologic effects were observed after 52 weeks of continuous inhalation exposure at 0.08 and 0.10 mg/m^3 of sulfuric acid mist.

protective suit, chemical (acid)-resistant gloves, such as neoprene, butyl rubber or polyethylene, chemical-resistant footwear plus socks, protective eyewear, dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with any N, R, P or HE filter, and a 5-day restricted entry interval (REI), designed to limit sulfuric acid exposure to handlers and post-application workers. Since EPA published the *Mineral Acids Human Health and Ecological Preliminary Risk Assessment for Registration Review for the Antimicrobial and Conventional Uses* dated June 23, 2016, for comment, the conclusions in the occupational handler section have been revised. Based on the desiccant properties of sulfuric acid, the corrosivity, and the lack of systemic toxicity concerns to the sulfate ions, the Agency has determined that a quantitative occupational risk assessment is not required for sulfuric acid to conclude with reasonable certainty that potential occupational exposures to sulfuric acid may pose a human-health risk of concern.

4. Characterization of Human Health Risks - Conventional Uses

Due to corrosivity of sulfuric acid to skin and eyes, dermal and inhalation PPE is required on labels for handlers and for post-application workers entering fields prior to the 5-day REI. Even though sulfuric acid is restricted use and PPE is required on all labels in order to decrease the likelihood of exposure, if sulfuric acid does come into contact with skin or eyes, there will be adverse effects. Since sulfuric acid rapidly dissociates in the environment, there is a low risk of concern for post-application exposures to worker re-entering treated areas after the 5-day REI. Based on potential occupational handler exposure to sulfuric acid, EPA has concluded that it may pose a human-health risk of concern.

5. Cumulative Risks

With respect to cumulative exposure, unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to any of the mineral acids listed in this case and any other substances and none of the mineral acids appear to produce a toxic metabolite produced by other substances. For the purposes of this *Mineral Acids Interim Registration Review Decision*, therefore, EPA has not assumed that mineral acids have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see http://www.epa.gov/pesticides/cumulative/.

6. Human Health Data Needs

The Agency required Product Use Information (GLN 875.1700) and Indoor Inhalation Exposure (GLN 875.1400) data in the mineral acids registration review GDCIs. As discussed earlier, these data are still under development by the AEATF II.

7. Human Incidents

Based on a search conducted on May 22, 2017, a total of 831 individual human health incidents have been reported for both the antimicrobial and conventional uses of the mineral acids in the Office of Pesticide Program's (OPP's) Incident Data System (IDS) for the time period spanning

from January 1, 2007 to May 22, 2017. A summary of the incidents is given in **Table 5**. The largest number of incidents (749) are associated with hydrochloric acid, followed by phosphoric acid (80) and sulfuric acid (2). In terms of severity, most of the incidents (758) were rated as HC (human moderate), followed by 35 rated as HA (human fatality), 32 rated as HB (human major), 4 rated as Human Minor (HD) and two rated as HE (severity unknown).

All 35 of the HA incidents were associated with the antimicrobial uses of hydrochloric acid and 31 of these were suicides. Suicides were typically conducted by mixing hydrochloric acid toilet bowl cleaner with lime sulfur to create fatal levels of hydrogen sulfide gas inside a vehicle. Three fatalities were associated with misuse where hydrochloric acid was mixed with bleach during bathroom cleaning. The remaining fatality was associated with an accident where a pool treatment worker spilled acid in a garage while trying to consolidate chemicals. He lost consciousness after hitting his head on the garage door while trying to escape and fell into the spill puddle.

Of the 78 phosphoric acid antimicrobial use incidents, the following exposure incidents were reported as: inhalation (28), dermal (26), ocular (19), and ingestion (5). Of the 28 inhalation exposure incidents, 12 were due to misuse (e.g., mixing the phosphoric acid product with bleach; cleaning employee using the incorrect respirator recommended by employer when applying product; employee untrained on how to apply product). Of the remaining 16 of 28 inhalation incidents, 7 were reported as applying the product in a confined area, such as an unventilated bathroom.

The two sulfuric acid incidents reported were due to conventional misuse. The two reported incidents were from residents complaining of odors coming from fields of mustards plants after they had been sprayed with sulfuric acid. The conventional sulfuric acid products are only registered as a potato vine desiccant, as they are not to be used on mustard plants.

Table 5 – Summary of Mineral Acid Human Health Incidents Since the RED

Active Ingredient	Number of Incidents					
	Human Fatality	Human Major	Human Moderate	Human Minor	Severity Unknown	Total
Hydrochloric Acid	35	29	679	4	2	749
Phosphoric Acid	0	3	75	0	0	78
Sulfuric Acid	0	0	2	0	0	2
Total of Above	35	32	758	4	2	831

In addition to the incidents reported in individual reports discussed above, there were 11,831 incidents that were reported in quarterly aggregate incident summaries. Most (11,587) of the incidents were for hydrochloric acid and the remainder (244) were for phosphoric acid. There were no aggregate incidents reported for sulfuric acid. In terms of severity, most of the incidents (11,809) were rated as HD and the remainder (22) were rated as HE.

8. Tolerances

Antimicrobial Exemptions for the Requirement of Tolerances

Mineral acids antimicrobial exemptions for the requirement of tolerances are set forth at 40 CFR §180.940 (b). The mineral acids tolerance exemptions are for dairy processing equipment, food processing equipment, and utensils for hydrochloric acid (limit of < 200 ppm), phosphoric acid (no limit), and sulfuric acid (limit of < 288 ppm). In addition, an exemption for the requirement of tolerance appears in 40 CFR §180.940 (c) for food processing equipment and utensils for sulfuric acid (limit of < 228 ppm).

Conventional Exemptions for the Requirement of Tolerances

Sulfuric acid has an exemption from the requirement of a tolerance when used in accordance with good agricultural practice in the production of garlic and onions, and for use as a potato vine desiccant in the production of potatoes (40 CFR §180.1019); however, the use of sulfuric acid in the production of garlic and onions is no longer registered.

B. Ecological Risk

An ecological risk assessment was not conducted for the antimicrobial uses of the four mineral acids. The compounds will dissociate in water to form the hydronium ion and chloride, phosphate or sulfate salts where they are ubiquitous in the environment. The hydronium ion may lower the pH of the aquatic system in some circumstances, but natural buffering of aquatic systems and dilution is expected to mitigate this potential effect.

The active ingredients of the mineral acids case for the antimicrobial uses are corrosive compounds and plants and animals that come into direct contact with the acid products will be harmed; however, the acids are expected to be diluted with water during use which will lead to the dissociation into hydronium ion and salts, and thus, not harming plants and animals.

For the agricultural use of sulfuric acid on potato vines, a qualitative ecological risk assessment was conducted. The Agency waived the sulfuric acid ecological effects data requirements during the Reregistration Eligibility Decision (RED) and no additional toxicity studies were required during Registration Review due to the caustic nature of the test chemical. Therefore, the registrant has not submitted any data to evaluate the eco-toxicological effects of sulfuric acid. As with the antimicrobial uses of sulfuric acid, plants and animals that come into direct contact with the 93% sulfuric acid product for potato vine desiccation will be harmed. However, the dissociation into the non-harmful hydronium ion and sulfate salts is expected to occur quickly after application.

1. Summary of Ecological Risks - Antimicrobial Uses

Aquatic Organisms

Mineral acids products are diluted with water during use. As the diluted mineral acids products

are rinsed down the drain, the acids will dissociate into hydronium ions and chloride, phosphate, or sulfate salts which are ubiquitous in the environment. The hydronium ion may lower the pH of the aquatic system in some circumstances, but dilution and natural buffering of aquatic systems are expected to mitigate this potential effect. There is no reasonable expectation for the antimicrobial uses of mineral acids to cause direct or indirect adverse effects to threatened and endangered species and no adverse modification of any designated critical habitat for such species is expected from the antimicrobial uses of mineral acids.

Terrestrial Organisms

Exposure of terrestrial species is unlikely because the mineral acids products are used to disinfect and sanitize surfaces in agricultural, residential, institutional, and medical premises and food processing equipment.

2. Summary of Ecological Risks - Conventional Uses

The single conventional use of sulfuric acid as a potato desiccant poses several primary environmental risks of concern: 1) the contamination of surface waters in close proximity to the field via spray drift, 2) direct exposure to wildlife and non-target organisms on the field during or shortly after application, and 3) aerial drift exposures that impact wildlife at considerable distances from treated fields. The other mineral acids (hydrochloric acid, phosphoric acid, and sodium bisulfate) do not have any conventional uses.

3. Characterization of Ecological Risks - Antimicrobial Uses

An ecological risk assessment is not necessary for the antimicrobial uses of the mineral acids chemical case.

4. Characterization of Ecological Risks - Conventional Uses

Aquatic Organisms

According to *Mineral Acids Human Health and Ecological Preliminary Risk Assessment for Registration Review for the Antimicrobial and Conventional Uses*, sulfuric acid may contaminate surface waters in close proximity to the field via spray drift. Once water bodies are contaminated with sulfuric acid, they could potentially, depending upon volume and concentration, be subject to changes in pH. Changes in pH in aquatic systems from input by sulfuric acid are expected to be within 2 pH units. The degree to which a change in pH will impact aquatic wildlife will depend on the magnitude of the pH change, which is expected to be highly variable, and the sensitivity of the particular organism or ecosystem to pH changes.

Terrestrial Organisms

The Agency assumes that terrestrial organisms that come in direct contact with the 93% sulfuric acid will experience corrosive effects of this chemical on tissue. Aerial exposures will impact wildlife farther from treated sites than ground exposures due to expected higher drift

concentrations and distances. Labeled application rates exceed 400 lbs a.i./Acre and as a result, on-field deposition is sufficient to impact on-field non-target organisms, and off-field spray drift deposition could be sufficient to impact non-target organisms at considerable distances from treated fields.

EPA believes that additional data may be necessary to fully evaluate risks to non-target terrestrial invertebrates, especially pollinators. Although EPA identified the need for certain data to evaluate potential effects to pollinators when initially scoping the registration review for sulfuric acid, the problem formulation and registration review DCI for sulfuric acid were both issued prior to EPA's issuance of the June 2014 *Guidance for Assessing Pesticide Risks to Bees.*[9] This 2014 guidance lists additional pollinator studies that were not included in the sulfuric acid registration review DCI. Therefore, EPA is currently determining whether additional pollinator data are needed for sulfuric acid. If the Agency determines that additional pollinator exposure and effects data are necessary to help make a final registration review decision for sulfuric acid, then EPA will issue a DCI to obtain these data. The pollinator studies that could be required for sulfuric acid are listed in **Table 6** below.

Table 6 - Potential Pollinator Data Requirements for Sulfuric Acid

Guideline #	Study
850.3020	Acute contact toxicity study with adult honey bees (Tier 1)
850.3030	Honey bee toxicity of residues on foliage (Tier 1)
Non-Guideline (OECD 213)	Honey bee adult acute oral toxicity (Tier 1)
Non-Guideline (OECD 237)	Honey bee larvae acute oral toxicity (Tier 1)
Non-Guideline	Honey bee adult chronic oral toxicity (Tier 1)
Non-Guideline	Honey bee larvae chronic oral toxicity (Tier 1)
Non-Guideline†	Field trial of residues in pollen and nectar (Tier 2)
Non-Guideline (OECD 75) †	Semi-field testing for pollinators (Tier 2)
850.3040†	Full-Field testing for pollinators (Tier 3)

† The need for higher tier tests for pollinators will be determined based upon the results of lower tiered tests and/or other lines of evidence and the need for a refined pollinator risk assessment.

5. Ecological Incidents

One ecological incident was reported for the mineral acids case in OPP's IDS (search of individual incidents and aggregate incidents conducted on August 31, 2017). One incident (I026233-001) is reported using a phosphoric acid product in May of 2014. Italian honey bees used to pollinate almond orchards were killed (adults) or deformed (newly hatched brood with the proboscis sticking out, deformed wings and twitching) after several products including pesticides (thiophanate-methyl and propiconazole), ACIDIpHACTANT (containing alkyl aryl polyoxyethylene phosphate esters, ethyl carboxylic acid, phosphoric acid, dimethylpolysiloxane), and CalMax (containing ammoniacal nitrogen, nitrate nitrogen, urea nitrogen, calcium, magnesium, boron, copper, iron, manganese, molybedenum, and zinc) were sprayed in the almond orchards. The dead and deformed bees were found three days after the bee hives (87 in

[9] http://www2.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

number) were moved from the almond orchards. Some hives were down to 4 frames of bees. The sprayed compounds were categorized as 'possible' causes of the bee mortalities and deformities.

There were no reported ecological incidents using sulfuric acid, hydrochloric acid and/or sodium bisulfate products in the IDS database.

C. Benefits Assessment

Antimicrobial Use Benefits

The use of mineral acids as sanitizers, disinfectants, virucides, disinfectants, microbiocides/ microbiostats, and fungicides is an indication of mineral acids' effectiveness for managing antimicrobial diseases. Mineral acids control microorganisms in eating establishments, food processing sites, animal premises, mushroom farms, hospitals and households, including bathrooms and kitchens. On hard non-porous surfaces, mineral acids control and/or kill public health organisms such as, but not limited to, bacteria (e.g., *Enterococcus faecalis*, Vancomycin-Resistant *Enterococci faecalis* [VRE], *Escherichia coli*, *Klebsiella pneumoniae, Mycobacterium bovis BCG*, *Pseudomonas aeruginosa*, *Salmonella enterica*, *Shigella dysenteriae, Staphylococcus aureus*, Methicillin-Resistant *Staphylococcus aureus* [MRSA], and *Enterobacter aerogene*s), viruses (e.g., Hepatitis A Virus, Human Immunodeficiency Virus [HIV] type 1, Poliovirus type 1, Rotavirus WA, Adenovirus type 2, Herpes Simplex type 1 and influenza A2/Hong Kong) and fungi (e.g., *Aspergillus niger* and *Trichophyton mentagrophytes* [athlete's foot fungus]).

Alternatives to mineral acids include peroxy compounds, alkyl dimethyl benzyl ammonium chloride (ADBAC), and dimethyl dialkyl ammonium chloride (DDAC). Similar to mineral acids, the chemical cases peroxy compounds (case 4072), ADBAC (case 0350) and DDAC (case 3003)[10] have comparable acute inhalation toxicity profiles and are also used as disinfectants, sanitizers, virucides, bacteriocides/bacteriostats, microbicides/microbistats, etc. in a wide range of settings, including agricultural premises/equipment, food handling/storage establishments, commercial, institutional and industrial premises/equipment, residential and public access premises, and medical premises and equipment. However, there are reports in the literature of work-related asthma, as well as human health incident asthma reports, associated with exposure to cleaning agents and disinfectants, and some of these reports relate to the use of the quaternary ammonium compounds (QACs), such as ADBAC and DDAC. These reports indicate that the use of QACs may pose a greater inhalation risk than mineral acids. Since the first 15-year cycle of the registration review process concludes in 2022, the Agency notes that several chemical cases are still under review in this registration review cycle involving alternative antimicrobial active ingredients to mineral acids.

[10] Documents pertaining to the registration review of peroxy compounds, ADBAC and DDAC can be accessed at http://www.regulations.gov in docket numbers EPA-HQ-OPP-2009-0546 (peroxy compounds), EPA-HQ-OPP-2015-0737 (ADBAC) and EPA-HQ-OPP-2015-0740 (DDAC).

Conventional Use Benefits

Products containing sulfuric acid are only registered for use west of the Mississippi River as a desiccant of potato vines. Potato vine killing is done either by physical removal, burning, and/or chemical desiccation that stops the bulking or growth of the potato tuber (e.g., Brazil, 2012[11]; Zotarelli et al., 2016[12]). Vine removal also separates the tubers from rhizomes and stolons, thereby making harvesting easier with less wear on machinery (UNebraska, undated[13]). Importantly, removal of vines helps reduce the spread of pathogens from the vines to the tubers, which in turn, can reduce storage rot. Late blight, early blight, bacterial soft rot, and virus diseases can be better managed with vine-desiccation. In addition, for potatoes to store properly and for processing, tubers must be physiologically mature. Vine-kill stops nutrients from moving from the vine to the tuber, allowing potato skin to harden (about three weeks after vines are killed) and better protect the tuber, especially from storage pathogens that enter through breaks in the potato skin.[1] In addition to sulfuric acid, there are other desiccants, such as diquat, paraquat, carfentrazone, and glufosinate.

Sulfuric acid is used to stop tuber development at the end of the season to optimize harvesting and enhance tuber quality for storage or processing. Sulfuric acid has characteristics that make it advantageous over other products in some situations. It provides an immediate vine-kill and kills pathogen spores, such as those causing late blight, on the soil surface that it contacts. It may be applied a second time 5 days after the first application, which may be necessary if vines are thick and the chemical does not fully penetrate the canopy. Other desiccants may require one to two weeks before second applications can be made. Sulfuric acid can also be used across a wider range of environmental conditions, such as temperature, compared to other desiccants. There are no rotational crop restrictions. The disadvantage of sulfuric acid is that unlike commonly used herbicide desiccants, the vine-kill is so rapid that the tubers do not mature or "set skin" (harden) as well. However, use of paraquat can lead to decay of tubers in storage; paraquat and carfentrazone cannot be used for potatoes that will be kept for seed, which farmers often do.

IV. Interim Registration Review Decision

A. Risk Mitigation Measures and Regulatory Rationale

In evaluating potential risk mitigation for mineral acids, EPA considered the risks, the benefits, and the use patterns of these compounds. As indicated in Appendix D, the Agency has made a “no effect” determination under ESA for mineral acids antimicrobial uses. For mineral acids conventional uses, the Agency is not making a finding under ESA at this time, In addition, the Agency is not making a determination on EDSP or pollinator risks. For antimicrobial uses, amendments to labels are required for the occupational uses of phosphoric acid products and sulfuric acid EPA Reg. No. 90863-1 due to occupational handler inhalation risks of exposure. There is no need for additional risk mitigation for any other mineral acids products with other

[11] Brazil, E. 2012. Desiccant decisions. Spudman, May/June, 2012.
[12] Zotarelli, L. Sargent, S., Dittmar, P., and Makani, M. 2016. Potato vine killing or desiccation. University of Florida Extension, Publ. HS925. http://edis.ifas.ufl.edu/pdffiles/HS/HS 18100.pdf
[13] http://cropwatch.unl.edu/potato/dessication_chemical; http://cropwatch.unl.edu/potato/desiccation_why_and_when

antimicrobial use scenarios, including but not limited to mopping, brushing, immersion, circulation, etc. To address potential human health and ecological risks of concern for the conventional use on potatoes, the Agency is requiring risk mitigation measures to reduce the potential for exposure to humans and wildlife.

1. Human Health Risks – Antimicrobial Uses

To address the potential for occupational risk from the spray and wipe application of phosphoric acid products and sulfuric acid EPA Reg. No. 90863-1, the Agency discussed and agreed upon the required risk mitigation with the Phosphoric Acid Steering Committee/Joint Venture, and the remaining phosphoric acid chemical companies and sulfuric acid EPA Reg. No. 90863-1's Phresh Technologies, LLC.

Occupational Handlers – Spray and Wipe Use

Due to the occupational handler inhalation risks of exposure from the spray and wipe application of phosphoric acid products and sulfuric acid EPA Reg. No. 90863-1, the Agency is requiring that labels be amended to mitigate those risks. The Agency requires that respiratory PPE for handlers in industrial facilities be added to the following eight labels: EPA Reg. Nos. 875-85, 875-184, 875-185, 1677-100, 3862-128, 4959-29, 5741-23, and 90863-1 (see **Table 7** and Appendices A and B). As shown in **Table 4**, the spray and wipe use scenario for phosphoric acid results in potential inhalation risks of concern (MOE is 2 and Target MOE is 30). As for sulfuric acid EPA Reg. No. 90863-1's spray and wipe use, the inhalation MOE is anticipated to be similar to that of phosphoric acid, and also poses a potential risk of concern. As previously discussed, inhalation toxicity data from sulfuric acid (Alarie et al., 1973) were used to assess the inhalation route of exposure for phosphoric acid. Unless phosphoric acid inhalation toxicological data are submitted, the Agency will continue to bridge the sulfuric acid data to the phosphoric acid inhalation risk assessment.

Inhalation MOEs were calculated for all EPA registered phosphoric acid products and sulfuric acid EPA Reg. No. 90863-1 with the spray and wipe application method stated on their labels, and the following respiratory PPE risk mitigation is required to be added to the eight EPA Reg. Nos. with a MOE under the Target MOE of 30. A NIOSH approved (TC-84A) filtering face-piece respirator is required for EPA Reg. Nos. 875-85, 875-184 and 4959-29. A NIOSH approved (TC-84A) elastomeric half face respirator with a N-95 filter is required for EPA Reg. Nos. 3862-128 and 5741-23. A NIOSH approved (TC-84A) full face respirator with a P100 filter is required for EPA Reg. Nos. 875-185, 1677-100 and 90863-1. The Agency notes that EPA Reg. No. 1677-100's label indicates an application rate of 8.7%, which is above the application rate protected by the full face respirator (up to 6.5%). In addition, EPA Reg. No. 1677-100's inhalation MOE with a full face respirator is 22.5, which is under the target MOE of 30. However, EPA Reg. No. 1677-100 is used as a foam application. As previously stated in Section III. A. 2., the foam application method is anticipated to have less exposure than the spray and wipe application method; however, the foam application method is considered an aerosol application and will be treated as such. As a result, the Agency decided that EPA Reg. No. 1677-100 may remain as a registered product; however, the foam application method inhalation MOEs are still potential risks of concern and a full face respirator is required.

Table 7 - Calculations for Respiratory PPE for Phosphoric Acid and Sulfuric Acid Products (Containing Antimicrobial Uses) with Spray and Wipe Scenario

Reg. Number	Highest Spray Application Rate on Product Label (%)[A]	Spray/Wipe Inhalation MOE without PPE Mitigation (Target MOE = 30)[B]	Protection Factor (PF)[C]	Required Respiratory PPE Mitigation[D]	Spray/Wipe Inhalation MOE with PPE Mitigation[E] (Target MOE = 30)
875-85	**0.23**	**16.6**	PF-5	Filtering face-piece respirator	83
875-100	0.12	33.93	N/A	None	N/A
875-182	0.06	62.4	N/A	None	N/A
875-184	**0.29**	**13.45**	PF-5	Filtering face-piece respirator	67.25
875-185	**1.8**	**2.17**	PF-50	Full face respirator	108.5
1677-58	.01	390	N/A	None	N/A
1677-90	0.06	62.92	N/A	None	N/A
1677-100	**8.7**	**0.45**	PF-50	Full face respirator	**22.5**
3862-128	**1.2**	**3.25**	PF-10	Elastomeric half face respirator	32.5
4959-9	0.06	62.4	N/A	None	N/A
4959-21	0.02	217	N/A	None	N/A
4959-23	0.01	312.98	N/A	None	N/A
4959-29	**0.16**	**24.96**	PF-5	Filtering face-piece respirator	124.8
4959-36	0.01	262.73	N/A	None	N/A
5741-23	**1.2**	**3.25**	PF-10	Elastomeric half face respirator	32.5
63838-14	0.07	62.4	N/A	None	N/A
65001-1	0.08	49.92	N/A	None	N/A
82808-3	0.06	62.92	N/A	None	N/A
90863-1	**1.97**	**2**	PF-50	Full face respirator	100

A. Percent a.i. of phosphoric acid in product / Dilution in water
B. Target MOE (30) / (Application Rate / Concentration to Yield Target MOE of 30 (0.13%))
C. If application rate is > 0.13%, a respirator is required.
   - Concentration to Yield Target MOE of 30 (0.13%) * PF-5 (5) = 0.65%. If application rate is < 0.65% and > 0.13%, a PF of 5 is required.
   - Concentration to Yield Target MOE of 30 (0.13%) * PF-10 (10) = 1.3%. If application rate is < 1.3% and > 0.65%, a PF of 10 is required.
   - Concentration to Yield Target MOE of 30 (0.13%) * PF-50 (50) = 6.5%. If application rate is < 6.5% and > 1.3%, a PF of 50 is required.
D. NIOSH approved (TC-84A) respirator according to the PF.
E. Spray/wipe inhalation MOE without PPE mitigation * PF number

Residential Handlers – Spray and Wipe Use

As shown in **Table 3**, the spray and wipe use scenario for phosphoric acid results in potential inhalation risks of concern (MOE is 17 and Target MOE is 30); however, due to the uncertainties discussed in Section III. A. 2., the Agency is not implementing mitigation. As previously stated, the Agency used AEJV survey results that collected data on the amount of product handled by homeowners on the following surfaces: sinks, tub/shower/shower door, and counter. According to the *Mineral Acids Human Health and Ecological Preliminary Risk Assessment for Registration Review for the Antimicrobial and Conventional Uses*, it is reasonable to assume that a handler would potentially clean all surfaces in a single day, and therefore, the exposure/risk has also been presented as the sum of a "daily cleaning" event. However, although the Agency used AEJV survey results, there are uncertainties because the results of the survey are still under review, and at this time, maximum amounts handled are used, which may overestimate exposure.

As stated in Section III. A. 6., of the 78 phosphoric acid human health incidents, 28 were reported as inhalation exposure incidents in IDS for the time period spanning from January 1, 2007 to May 22, 2017. Out of the 28 incidents, 12 were due to misuse. Of the remaining 16 incidents, 7 were reported as applying the product in a confined area, such as an unventilated bathroom. The Agency notes that the minimal number of reported phosphoric acid inhalation incidents indicate that minimal risk mitigation be applied to the phosphoric acid inhalation use scenarios.

The first 15-year cycle of the registration review process concludes in 2022. The Agency notes that several chemical cases are currently under review in this registration review cycle, including alternative active ingredients to mineral acids. Upon completion of alternative active ingredient risk assessments, the Agency anticipates that refined risk mitigations may be added in the mineral acids final decision during this registration review cycle.

2. Human Health Risks – Conventional Uses

Occupational Handlers

Due to the highly corrosive nature of sulfuric acid, EPA is requiring additional PPE in order to

reduce the potential for risk to handlers. Currently, labels require handlers mixing, loading, and applying sulfuric acid to wear chemical resistant coveralls, goggles and a face shield, chemical-resistant gloves and boots. Based on conversations with registrants, additional measures are already in place in the field to protect workers and handlers, such as closed cabs. Many applicators also currently have additional water available in case there is a spill or leak according to registrants. Also, there have been a low number incidents reported due to the use of sulfuric acid. The benefits of sulfuric acid as a potato vine desiccant are high due to the rapid vine kill it provides, making harvesting easier and reducing the spread of pathogens from the vines to tubers. However, it is almost never applied aerially; the available market research data suggest that aerial applications of sulfuric acid are made to less than 1% of acres treated with sulfuric acid.

EPA mineral acids labels with conventional uses must be amended with the following requirements to reduce the likelihood of exposure and therefore the potential risk to occupational handlers (see Appendices A and C):

- Require closed mixing and loading systems.
- Require a closed cab for all ground applications.
- Prohibit the use of aerial application equipment.
- At least 100 gallons of water on supply trucks and 30 gallons on the application equipment must be immediately available to drench anyone who may come into contact with the pesticide.

The impacts associated with prohibiting aerial application are likely to be low due to the small number of acres treated aerially with sulfuric acid (less than 1 percent of sulfuric acid treated acres). However, the requirement of closed mixing and loading systems could adversely impact sulfuric acid users that do not currently own closed mixing and loading systems. It is not known how many users would be impacted by the requirement but there would be an increased cost to purchase the equipment to mix and load sulfuric acid. According to available usage data, almost 83 percent of the area treated with sulfuric acid is treated by commercial applicators while about 16% of the area is treated by the farmer. Commercial certified applicators will likely have closed mixing and loading systems but private certified applicators (farmers) may not, though growers could also invest in a closed pesticide delivery system. Giles and Billing (2013)[14] estimate the cost of a simple closed system for loading pesticides to be about $330.

3. Ecological Risks – Conventional Uses

EPA is prohibiting aerial application of sulfuric acid to reduce the concentrations and distances of off-field spray drift to address potential human health risk concerns. Exposure to non-target aquatic and terrestrial organisms would be reduced by limiting the conventional use of sulfuric acid to ground application. As mentioned above, the available pesticide market research data suggest that aerial applications of sulfuric acid to potatoes are made to less than 1% of acres treated with sulfuric acid. Due to the low reliance on aerially applied sulfuric acid and, thus, the

[14] Giles, K., and R. Billing. 2013. Designs and Improvements in Closed Systems. Report to the California Department of Pesticide Regulations. University of California at Davis, Department of Biological and Agricultural Engineering. 13 p.

low economic impact of prohibiting that application method, the potential for ecological exposure due to drift outweighs its benefit.

For ground applications, current labels contain outdated drift language. Therefore, the Agency is requiring this following drift text to be added to all sulfuric acid labels:

- Apply with a nozzle height no more than 4 feet above the ground or crop canopy.
- Applicators are required to use a Medium or coarser droplet size (ASABE S572.1).
- Do not apply when wind speeds exceed 10 miles per hour at the application site.
- Do not apply during temperature inversions.

V. Next Steps and Timeline

A. Interim Registration Review Decision

In accordance with 40 CFR Sections 155.56 and 155.58, the Agency is issuing the *Mineral Acids Interim Registration Review Decision.* A Federal Register Notice will announce the availability of this Interim Decision. Data remain to be submitted to the Agency and are currently under development by the AEATF II; however, upon receipt and review of these data, the Agency may, as appropriate, reevaluate the immersion and coarse spray treatment. According to Section IV. A., mineral acids registrants will be required to submit amended labels. As indicated in Section III. B. 4. and Appendices D and E, the Agency's final registration review decision for mineral acids will be dependent upon the result of the Agency's ESA assessment and any necessary consultation with the Services, an EDSP FFDCA section 408(p) determination, and an assessment of non-target exposure to pollinators (bees).

B. Implementation of Mitigation Measures

Once the *Mineral Acids Interim Registration Review Decision* is issued in final form, mineral acids registrants will be required to submit amended labels that include the label changes described in Appendices B and C. The amended labels are required to be submitted to the Agency for review within 60 days following issuance of the Interim Registration Review Decision.

VI. Appendices

Appendix A: Summary of Required Actions for Phosphoric and Sulfuric Acids

Registration Review Case: 4064 **PC Codes: 076001 and 078001** **Chemical Type: Sanitizers, disinfectants, virucides, disinfectants, microbiocides/microbiostats, fungicides, and potato vine dessicant**					
Affected Population(s)	**Source of Exposure**	**Route of Exposure**	**Duration of Exposure**	**Potential Risk(s) of Concern**	**Required Label Changes**
• Occupational handlers – antimicrobials use	• Air	• Inhalation	• Sub-chronic	• Inhalation effects	• Add PPE
• Occupational handlers – potato use	• From application to potatoes	• Inhalation and dermal	• Acute	• Inhalation and dermal effects	• Closed mixing/loading • Closed cabs • Prohibit aerial • Additional water required for decontamination
• Wildlife	• Residues in and near fields from application to potatoes	• Dermal and oral	• Acute	• Oral and dermal effects	• Prohibit aerial • Spray drift restrictions

Appendix B: Required Labeling Changes for Phosphoric Acid and Sulfuric Acid Products Containing Antimicrobial Uses

Description	Required Amended Label Language for End-Use Products	Placement on Label
Respiratory Protection for EPA Registration Numbers: • 875-85 • 875-184 • 4959-29	"PERSONAL PROTECTIVE EQUIPMENT: Handlers in industrial facilities using the spray and wipe application method must wear a NIOSH approved (TC-84A) filtering face-piece respirator."	Precautionary Statements under the heading "Hazards to Humans and Domestic Animals"
Respiratory Protection for EPA Registration Numbers: • 3862-128 • 5741-23	"PERSONAL PROTECTIVE EQUIPMENT: Handlers in industrial facilities using the spray and wipe application method must wear a NIOSH approved (TC-84A) elastomeric half face respirator with a N-95 filter."	Precautionary Statements under the heading "Hazards to Humans and Domestic Animals"
Respiratory Protection for EPA Registration Numbers: • 875-185 • 1677-100 • 90863-1	"PERSONAL PROTECTIVE EQUIPMENT: Handlers in industrial facilities using the spray and wipe application method must wear a NIOSH approved (TC-84A) full face respirator with a P100 filter."	Precautionary Statements under the heading "Hazards to Humans and Domestic Animals"

Appendix C: Required Labeling Changes for Sulfuric Acid Products Containing Conventional Uses

Description	Required Amended Label Language for End-Use Products	Placement on Label
Engineering Controls for Mixers and Loaders	"Engineering Controls: Mixers and loaders must use a closed system that meet the requirements listed in the WPS for agricultural pesticides [40 CFR 170.607(d)(2)(i) &(ii)] for dermal and inhalation protection. At any disconnect point, the system must be equipped with a dry disconnect or dry couple shut-off device that is warranted by the manufacturer to minimize drippage to no more than 2 ml per disconnect. Mixers and loaders must: -- wear the following PPE: *long-sleeve shirt, long pants, shoes, socks, chemical-resistant gloves, and chemical-resistant apron*, -- wear protective eyewear, if the system operates under pressure, and -- be provided and must have immediately available for use in an emergency, such as a broken package, spill, or equipment breakdown: chemical-resistant footwear plus socks, and respirator as described in the ***Respirator*** section of this label."	Precautionary Statements under the heading "Hazards to Humans and Domestic Animals"
Respiratory Protection	"***Respirator*** When a respirator is required, handlers must wear a minimum of an elastomeric half face NIOSH approved respirator with any N[1], R or P filter (TC-84A), OR a full face NIOSH	Precautionary Statements under the heading "Hazards to Humans and Domestic Animals"

	approved particulate respirator with any N[1], R or P filter (TC-84A); OR a NIOSH approved powered air purifying respirator with an HE filter (TC-21C)." [1]*Note to registrant: Drop the "N" option if there is oil in the product's formulation and/or the product is labeled for mixing with oil-containing products.*	
Engineering Controls for Applicators	"Engineering Controls: Applicators using motorized ground equipment must use an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.305] for dermal and inhalation protection. In addition, applicators must: -- wear the following PPE: *long-sleeve shirt, long pants, shoes, socks,* -- be provided and have immediately available for use in an emergency when they must exit the cab in the treated area: *coveralls, chemical-resistant gloves, chemical-resistant footwear, chemical-resistant headgear, if overhead exposure,* respirator as described in the ***Respirator*** section of this label -- take off any PPE that was worn in the treated area before reentering the cab, and -- store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab."	Precautionary Statements under the heading "Hazards to Humans and Domestic Animals"
Aerial Prohibition	"Aerial applications are prohibited. Only apply this product using motorized ground equipment."	Directions for Use

Decontamination	"At a minimum, 100 gallons of water must be secured to supply trucks during mixing and loading operations. At a minimum, 30 gallons must be attached to the pesticide application vehicle at all times of pesticide application."	Directions for Use
Enforceable Spray Drift Management Language	"SPRAY DRIFT Ground Boom Applications • User must only apply with the nozzle height recommended by the manufacturer, but no more than 4 feet above the ground or crop canopy. • Applicators are required to use a Medium or coarser droplet size (ASABE S572.1). • Do not apply when wind speeds exceed 10 miles per hour at the application site. • Do not apply during temperature inversions."	Directions for Use in a box titled "Spray Drift" under the heading "Ground Boom Applications"
Advisory Spray Drift Management Language	**"SPRAY DRIFT ADVISORIES** THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT. BE AWARE OF NEARBY NON-TARGET SITES AND ENVIRONMENTAL CONDITIONS. **IMPORTANCE OF DROPLET SIZE** An effective way to reduce spray drift is to apply large droplets. Use the largest droplets that provide target pest control. While applying larger droplets will reduce spray drift, the potential for drift will be greater if applications are made improperly or under unfavorable environmental conditions.	Directions for Use, just below the Spray Drift box, under heading "Spray Drift Advisories"

	Controlling Droplet Size – Ground Boom *(**note to registrants:** remove if ground boom is prohibited on product labels)* • Volume - Increasing the spray volume so that larger droplets are produced will reduce spray drift. Use the highest practical spray volume for the application. If a greater spray volume is needed, consider using a nozzle with a higher flow rate. • Pressure - Use the lowest spray pressure recommended for the nozzle to produce the target spray volume and droplet size. • Spray Nozzle - Use a spray nozzle that is designed for the intended application. Consider using nozzles designed to reduce drift. **BOOM HEIGHT – Ground Boom** *(**note to registrants:** remove if ground boom is prohibited on product labels)* Use the lowest boom height that is compatible with the spray nozzles that will provide uniform coverage. For ground equipment, the boom should remain level with the crop and have minimal bounce. **SHIELDED SPRAYERS** Shielding the boom or individual nozzles can reduce spray drift. Consider using shielded sprayers. Verify that the shields are not interfering with the uniform deposition of the spray on the target area.	

	TEMPERATURE AND HUMIDITY When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation. **TEMPERATURE INVERSIONS** Drift potential is high during a temperature inversion. Temperature inversions are characterized by increasing temperature with altitude and are common on nights with limited cloud cover and light to no wind. The presence of an inversion can be indicated by ground fog or by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing. Avoid applications during temperature inversions. **WIND** Drift potential generally increases with wind speed. AVOID APPLICATIONS DURING GUSTY WIND CONDITIONS. Applicators need to be familiar with local wind patterns and terrain that could affect spray drift.”	

Appendix D: Endangered Species Assessment

Antimicrobial Assessment

The Agency has made a "no effect" determination under the Endangered Species Act (ESA) for mineral acids antimicrobial uses for all listed species and designated critical habitat for such species and has therefore concluded that consultation with the Fish and Wildlife Service and the National Marine Fisheries Service under ESA section 7(a)(2) is not required. Unless public comments provide new information or data that warrant such assessment, no additional environmental risk assessment of the antimicrobial uses is needed in support of this registration review.

Conventional Assessment

For the conventional use of sulfuric acid as a desiccant for potato vines, nontarget plants and animals coming into direct contact with the acid products during spraying may be harmed due to the corrosive nature of the compound. Further, sulfuric acid may contaminate surface waters in close proximity to the field by way of spray drift and may lower the pH of the surface waters depending upon water volume and acid concentration. The Agency is not making a finding under ESA at this time due to the potential direct contact of plants and animals during application to potato vines and the potential for aquatic pH changes from desiccant use spray drift.

In November 2013, the EPA, along with the Services and the United States Department of Agriculture (USDA), released a summary of their joint Interim Approaches for assessing risks to endangered and threatened (listed) species from pesticides. The Interim Approaches were developed jointly by the agencies in response to the National Academy of Sciences' (NAS) recommendations and reflect a common approach to risk assessment shared by the agencies as a way of addressing scientific differences between the EPA and the Services. The NAS report[15] outlines recommendations on specific scientific and technical issues related to the development of pesticide risk assessments that EPA and the Services must conduct in connection with their obligations under the ESA and FIFRA.

As part of a phased, iterative process for developing the Interim Approaches, the agencies will also consider public comments on the Interim Approaches in connection with the development of upcoming Registration Review decisions. The details of the joint Interim Approaches are contained in the white paper *Interim Approaches for National-Level Pesticide Endangered Species Act (ESA) Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report*[16], dated November 1, 2013.

Given that the agencies are continuing to develop and work toward implementation of the Interim Approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, the ecological risk assessment supporting this *Mineral Acids Interim*

[15] *Assessing Risks to Endangered and Threatened Species from Pesticides.* Available at http://www.nap.edu/catalog.php?record_id=18344
[16] Available at http://www2.epa.gov/endangered-species/assessing-pesticides-under-endangered-species-act#report

Registration Review Decision does not contain a complete ESA analysis that includes effects determinations for specific listed species or designated critical habitat. Although EPA has not yet completed effects determinations for specific species or habitats for this *Mineral Acids Interim Registration Review Decision*, EPA's evaluation assumed for all taxa of non-target wildlife and plants that listed species and designated critical habitats may be present in the vicinity of the application of mineral acids. This assessment will allow EPA to focus its future evaluations on the types of species where the potential for effects exists once the scientific methods being developed by the agencies have been fully vetted. Once the agencies have fully developed and implemented the scientific methodology for evaluating risks for listed species and their designated critical habitats, these methods will be applied to subsequent analyses for mineral acids as part of completing this registration review.

Appendix E: Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision for mineral acids, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), mineral acids are subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013[17] and includes some pesticides scheduled for registration review and chemicals found in water. Mineral acids active ingredients are not currently scheduled for screening. However, it should be noted that mineral acids will be screened for their potential to interact with the endocrine system. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website.[18]

In this interim decision, EPA is making no human health or environmental safety findings associated with the EDSP screening of mineral acids. Before completing the registration review for mineral acids, the Agency will make an EDSP FFDCA section 408(p) determination.

[17] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[18] http://www.epa.gov/endo/